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The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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*Ex parte* JAY C. BUCKEY,
LARRY R. BROWN, and DONNA L. ALVARENGA

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Appeal 2009-012389
Application 10/786,429
Technology Center 1600

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Decided: March 8, 2010

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Before ERIC GRIMES, LORA M. GREEN, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving a method of treating motion sickness. The Examiner has rejected the claim as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

## STATEMENT OF THE CASE

Claim 1 is on appeal and reads as follows:

1. A method for decreasing the signs and symptoms of motion sickness comprising administering to a subject an effective amount of a halogenated pheniramine to decrease the signs or symptoms of motion sickness, wherein said halogenated pheniramine consists of chlorpheniramine or enantiomers thereof, wherein said halogenated pheniramine is administered orally or topically, and wherein said halogenated pheniramine is administered at a dose of 12 mg.

## OBVIOUSNESS

*Issue*

The Examiner has rejected claim 1 under 35 USC § 103(a) as being obvious in view of Ueno,[1] Drug Information Handbook,[2] British Medical Journal,[3] Weinstein,[4] and Kohl.[5]

The Examiner finds that Ueno discloses the "treatment of S. murinus [the house musk shrew] by administering 20mg/kg of chlorpheniramine in treating motion sickness" (Answer 3). The Examiner finds that the Drug Information Handbook discloses "the human dosage of chlorpheniramine as 8-12mg every 8-12 hours" (*id.* at 4). The Examiner finds that the British Medical Journal discloses antihistamines for the treatment of vomiting, a symptom of motion sickness, and that Weinstein and Kohl disclose the use

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[1] Ueno et al., 43 *Life Sciences* 413-420 (1988)
[2] *Drug Information Handbook*, 2nd Edition, Lexi-Comp Inc., Hudson, Ohio (1994-95)
[3] *British Medical Journal*, pp. 481-483 (21 Feb. 1970).
[4] Weinstein et al.,68 *Aviat. Space Environ. Med.* 890-894 (1997) (abstract only)
[5] Kohl et al., 62 *Aviat. Space Environ. Med.* 392-396 (1991) (abstract only)

of antihistamines for the treatment of motion sickness. The Examiner concludes that "[o]ne of ordinary skill in the art would have been motivated to employ chlorpheniramine orally in a dosage of 12 mg in a method of treating motion sickness" because a human oral dosage of 12 mg of chlorpheniramine is known and other antihistamines are known to be administered orally to treat motion sickness (*id.*).

Appellants contend that the cited references do not suggest an oral or topical 12 mg dose of chlorpheniramine to treat motion sickness because Ueno discloses a much higher dose, administered subcutaneously, to achieve the treatment of motion sickness in an animal model (Appeal Br. 8; Reply Br. 3).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that the cited references suggest an oral or topical 12 mg dose of chlorpheniramine to treat motion sickness?

*Findings of Fact*

1. Ueno discloses that "motion sickness and effects of possible prophylactic drugs were studied using Suncus murinus (house musk shrew)" (Ueno 413)

2. Ueno discloses that the subcutaneous injection of chlorpheniramine[6] (20 mg/kg) "decreased the emetic effect of motion sickness" (*id.*).

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[6] Ueno actually refers to the relevant drug as "chlorphenylamine," but Appellants acknowledge that Ueno discloses administering chlorpheniramine to treat motion sickness (Appeal Br. 8).

3. The Drug Information Handbook discloses that chlorpheniramine is used to treat symptoms of allergies (Drug Information Handbook 197).

4. The Drug Information Handbook discloses the following "Usual Dosage[s]" of chlorpheniramine:

> Children ... 6-12 years: 2 mg every 4-6 hours, not to exceed 12 mg/day or sustained release 8 mg at bedtime
> Children > 12 years and Adults: Oral: 4 mg every 4-6 hours, not to exceed 24 mg/day or sustained release 8-12 mg every 8-12 hours, not to exceed 24 mg/day

(*Id.* at 198.)

5. The Drug Information Handbook discloses that chlorpheniramine is available in various dosage forms, of which the strongest capsule and tablet dosages are 12 mg (*id.*).

6. The British Medical Journal discloses that antihistamines are used to treat vomiting (British Medical Journal, 483, Table I).

7. Weinstein discloses that the "most common pharmacological agents for alleviating symptoms of motion sickness in the U.S. are over-the-counter antihistamines" (Weinstein, abstract).

8. Kohl discloses that terfenadine, an antihistamine, was effective for the treatment of motion sickness (Kohl, abstract).

*Principles of Law*

"[I]t is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456 (CCPA 1955).

"Obviousness does not require absolute predictability of success… For obviousness under § 103, all that is required is a reasonable expectation of success." *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988).

*Analysis*

Claim 1 is directed to a method for treating motion sickness by orally or topically administering a 12 mg dose of chlorpheniramine.

Ueno discloses that the subcutaneous injection of 20 mg/kg of chlorpheniramine, an antihistamine, decreased vomiting in an animal model of motion sickness. The Drug Information Handbook discloses the use of oral chlorpheniramine to treat allergies, in adult dosages of 8-12 mg every 8-12 hours, and that chlorpheniramine is sold in dosage forms including 12 mg capsules and tablets. The British Medical Journal, Weinstein and Kohl disclose that antihistamines are used to treat vomiting and motion sickness. In view of these disclosures, it would have been obvious to one of skill in the art to administer an oral 12 mg dose – the strongest standard capsule or tablet dosage – of chlorpheniramine to a subject to treat motion sickness.

Appellants contend that the cited references do not suggest a 12 mg dose of chlorpheniramine to treat motion sickness because Ueno discloses a much higher dose, administered subcutaneously, to achieve the treatment of motion sickness in an animal model (Appeal Br. 8; Reply Br. 3). Appellants contend that Ueno's 20 mg/kg dosage is equivalent to a dosage of 1400 mg in a 70 kg human subject (Reply Br. 3).

This argument is not persuasive. Ueno does not purport to disclose an optimized or minimum effective dose of chlorpheniramine for the treatment of motion sickness, but only discloses that a single, subcutaneously administered dosage was shown to be effective. The Drug Information Handbook discloses that an orally administered 12 mg dose of chlorpheniramine is commonly used to treat symptoms of allergies. The

Drug Information Handbook also discloses that 12 mg of chlorpheniramine is the maximum daily dosage for children 6-12 years old, and that a 12 mg dose is the strongest standard oral dosage form. Thus, the references would have suggested, to a person of ordinary skill in the art, administering a 12 mg oral dosage of chlorpheniramine for the treatment of motion sickness. In accord with *In re Aller*, the determination of optimum or workable ranges by routine experimentation is not inventive.

To the extent Appellants are arguing that one of skill in the art would not have had a reasonable expectation of success in using a 12 mg dose of chlorpheniramine to treat motion sickness, this argument is not persuasive. In accord with *In re O'Farrell*, obviousness does not require an absolute predictability of success but only a reasonable expectation of success. The British Medical Journal, Weinstein, and Kohl all teach that antihistamines are used to treat vomiting and motion sickness. The Drug Information handbook discloses that 12 mg of chlorpheniramine is the strongest available capsule or tablet dosage form. Thus, based on the cited references, one of skill in the art would have reasonably expected that a 12 mg dose would be effective in the treatment of motion sickness.

*Conclusion of Law*

The evidence of record supports the Examiner's conclusion that the cited references suggest a 12 mg dose of chlorpheniramine to treat motion sickness.

## SUMMARY

We affirm the rejection of claim 1 under 35 USC § 103(a).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

alw

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